

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESAL PRICE
LITIGATION

MDL No. 1456

CIVIL ACTION: 01-CV-12257-PBS

Judge Patti B. Saris

THIS DOCUMENT RELATES TO
ALL CLASS ACTIONS

**PLAINTIFFS' MEMORANDUM IN OPPOSITION TO MOTION TO DISMISS
THE AMENDED CONSOLIDATED CLASS ACTION COMPLAINT AND IN
OPPOSITION TO THE DEFENDANTS' CONSOLIDATED MEMORANDUM
(REDACTED VERSION)**

TABLE OF CONTENTS

	<u>PAGE</u>
I. INTRODUCTION	1
II. THE ALLEGATIONS OF THE AMCC	2
A. General Allegations of Defendants' Fraudulent Schemes	3
B. The Government Investigations Into Defendants' AWP Scheme	5
C. Defendant-Specific Unlawful Conduct.....	7
D. The Pervasive Damage Caused by Defendants' AWP Scheme.....	8
E. Plaintiffs' Causes of Action	8
III. THE APPLICABLE STANDARD FOR DISMISSAL	9
IV. THE AMCC SATISFIES AND EXCEEDS THE REQUIREMENTS OF RULE 9(b)	10
A. The Requirements of Rule 9(b).....	10
B. The Court Specified How Plaintiffs Should Comply With Rule 9(b)	11
C. The AMCC Identifies Each Drug Targeted by Plaintiffs' Claims and Sufficiently Outlines the General Scheme to Defraud	11
D. The AMCC Sufficiently Outlines How the Fraud Is Carried Out in the PBM Context	13
E. The AMCC's Allegations of Additional Improper Inducements Are Specific and Sufficient.....	14
V. COUNTS I AND II PROPERLY PLEAD RICO VIOLATIONS	16
A. An Overview of Plaintiffs' Civil RICO Claims and Their Necessary Elements.....	16
B. The AMCC Properly Identifies the RICO Enterprises	17
1. The RICO "Enterprise" concept	17
2. The Manufacturer-Publisher Enterprises	18
a. Plaintiffs allege that each Manufacturer-Publisher Enterprise has an ongoing, continuing structure separate and apart from the racketeering activity	19

b.	Plaintiffs allege that each Manufacturer-Publisher Enterprise has a common purpose	22
3.	The Manufacturer-PBM Enterprises.....	25
a.	Plaintiffs allege that each Manufacturer-PBM Enterprise has an ongoing, continuing structure separate and apart from the racketeering activity	25
b.	Plaintiffs allege that each Manufacturer-PBM Enterprise has a common purpose.....	27
C.	The AMCC Properly Alleges That Defendants Conducted the Affairs of the Manufacturer-Publisher and Manufacturer-PBM Enterprises.....	28
D.	Plaintiffs Have Standing to Sue Defendants for RICO Violations	32
1.	Plaintiffs have adequately alleged direct injury to business or property.....	32
2.	There are no intervening acts that break <i>Holmes</i> causation.....	35
VI.	COUNT IX PROPERLY PLEADS CIVIL CONSPIRACY	38
A.	The AMCC States a Claim for a Concerted Action Civil Conspiracy	38
B.	The Civil Conspiracy Claim Complies With Rule 9(b).....	40
VII.	COUNT IV PROPERLY PLEADS VIOLATIONS OF STATE CONSUMER PROTECTION STATUTES.....	42
A.	Plaintiffs Have Properly Pled Causation.....	42
B.	Plaintiffs Have Properly Identified Defendants' Deceptive Practices.....	45
C.	Plaintiffs Have Standing to Sue Under the Consumer Statutes	47
D.	Plaintiffs Are Not Required to Plead Reliance	51
VIII.	THE AMCC PROPERLY INCLUDES MULTIPLE-SOURCE DRUGS IN THE AWP INFLATION SCHEME	52
A.	The AMCC's Detailed Allegations Regarding Multi-Source Drugs.....	52
B.	Defendants "We Have No Incentive" Argument Makes No Sense.....	54
IX.	CONCLUSION.....	58

I. INTRODUCTION

Plaintiffs' Amended Master Consolidated Class Action Complaint (the "AMCC") was carefully crafted in response to the Court's May 13, 2003 Memorandum and Order on Defendants' motions to dismiss (the "Order"). The AMCC meets, indeed exceeds, the letter of the requirements set forth in the Order. The substantial changes and augmentations embodied in the AMCC include:

- Narrowing the scope of the case to focus on approximately 321 specifically identified drugs. The AMCC also specifies the fraudulent AWP for each of these drugs, usually over multiple years. *See* ¶ 11 and Appendix A to the AMCC.
- Identifying a Plaintiff purchaser for each Defendant as required by the Court's order and a Plaintiff purchaser for most of the 321 specified drugs. *See* Appendix B to the AMCC.
- Substantially buttressing the specific allegations against each individual Defendant, largely based on Defendants' *own* documents produced in the many governmental investigations that have taken place and that, in large measure, continue to this day. *See* ¶¶ 200-540.
- Redefining the definition of the enterprises pled under the Racketeering Influenced and Corrupt Organizations Act to eliminate the so-called "hub-and-spoke" problem that concerned the Court, adding allegations as to the shared common purpose of the Defendants, the Publishers and the pharmacy benefit manufacturers ("PBMs") in conducting the operations of the AWP scheme. In addition, the AMCC expands the allegations related to Defendants' operation of the enterprises. *See* ¶¶ 619-79.
- More clearly detailing the allegations regarding multi-source and generic drugs, as the Court requested. *See* ¶¶ 179-90. Indeed, as the new allegations demonstrate, AWP fraud is most exacerbated for generic drugs, and for brand name drugs for which there are biological or therapeutic equivalents, sometimes resulting in an AWP 50,000% more than actual average costs. *See, e.g.,* ¶ 179-89.
- Adding new allegations of a conspiracy among certain Defendants to raise and fix AWP in connection with drugs covered by the "Together Rx Card Program" ("Together Card"). *See* ¶¶ 592-94, 604-18, 692-725, 734-41. Although new, these allegations – which have been extensively investigated over the course of several months – are closely related to the core AWP fraud at issue in this suit because the inflation of AWP is the touchstone of the Together Card conspiracy.
- Adding a new claim challenging the conspiracy formed between each Defendant Drug Manufacturer and each PBM that had the common purpose of perpetuating a reimbursement system based on AWP, because such a system financially benefits *both* the manufacturer and the PBM. *See* ¶ 729.

¹ Unless otherwise indicated, "¶" references paragraphs in the AMCC.

Despite these changes to the AMCC, Defendants raise five global challenges. First, Defendants raise again 9(b) as a basis for dismissal. As explained herein, the Court addressed 9(b) in the Order and the allegations of the complaint are tailored to comply with the Order. The Order required that Plaintiffs clearly and concisely allege (1) the specific drugs purchased from each Defendant, (2) the alleged AWP for each drug, and (3) the name of the Plaintiff that purchased the drug. The AMCC has satisfied each of these elements and no more is required.

Second, Plaintiffs have stated viable RICO claims. The fact there are a multitude of enterprises does not result in a “pleading game” and is not surprising given the scope of the unlawful conduct. Rather, the AMCC satisfies the enterprise requirements of First Circuit law and has properly pled a shared common purpose and the conduct of an enterprise by each Defendant. As to causation, Defendants’ documents quoted in the AMCC establish that Plaintiffs are the direct targets of the AWP scheme, and causation is thus established at the pleading stage.

Third, Plaintiffs have easily satisfied the pleading requirements for a civil conspiracy which only requires allegations that two or more co-conspirators combine to accomplish an unlawful purpose or to accomplish a purpose by unlawful means. Plaintiffs have pled both.

Fourth, Plaintiffs state law claims have already been sustained by this Court and adequately pled causation, as admitted to by Defendants’ own documents.

Finally, as to generic-multi-source drugs, the AMCC adequately alleges and details much of the AWP inflation scheme involving these drugs – indeed, AWP manipulation is most exacerbated where therapeutic equivalents exist.

Defendants’ latest motions should be denied in total.

II. THE ALLEGATIONS OF THE AMCC

The AMCC is brought by six third party payor Plaintiffs and five associational Plaintiffs, all acting on behalf of themselves and a proposed nationwide class of consumers, self-insured employers, health and welfare plans, health insurers and other end payors of prescription drugs

(the “Class”). The drugs purchased by each of these Plaintiffs are identified in Appendix B to the AMCC. The AMCC has four general parts: the general allegations (¶¶ 132-99, 541); the Defendant-specific allegations (¶¶ 200-540); allegations regarding the Together Card scheme (¶¶ 542-618);² and a statement of the claims for relief set forth in ten counts (¶¶ 619-741).

A. General Allegations of Defendants’ Fraudulent Schemes

Like the MCC before, the AMCC alleges that Defendants have engaged in a comprehensive scheme to vastly inflate the AWP that Defendants report to trade publications such as the *Red Book*, *MediSpan* and the *Blue Book* (the “Publishers”). See generally ¶¶ 133-90.³ Defendants inflate their AWP because they are aware that various participants in pharmaceutical reimbursement systems rely upon and use the AWP to establish reimbursement rates for all classes of prescription drugs, brand name and generic. ¶¶ 136-38, 172. The reimbursement systems adversely impacted include those operated by private health plans and government programs such as Medicare. ¶¶ 142-78.⁴

The AMCC also explains the extent to which AWP are utilized in private reimbursement systems. Health plans typically contract with fiscal intermediaries called pharmacy benefit managers – or “PBMs” – to administer and manage the prescription drug benefit. Four PBMs – Advance PCS, Caremark, Express Scripts and Medco Health – are responsible for administering the drug benefits of 210 million persons in the United States, or 70 percent of the nation’s population. For brand name drugs, these PBMs utilize the AWP set by drug manufacturers as the basis for reimbursement (i) made by health plans to the PBMs for their members’ drug

² The Together Card allegations are the subject of a separate motion and therefore will not be addressed in this memorandum.

³ See also *In re Pharm. Indus. Average Wholesale Price Litig.*, 263 F. Supp. 2d 172, 178-180 (D. Mass. 2003) (summarizing scheme) (hereinafter cited as “AWP”).

⁴ The Medicare Program generally does not cover the cost of self-administered prescription drugs and instead only provides reimbursement for approximately 450 drugs that are, generally, administered directly by a physician, including injectables, certain oral anti-cancer drugs and drugs furnished under a durable medical equipment benefit. ¶ 144. The drugs thus covered by Medicare Part B are referred to herein and in the AMCC as “Covered Drugs.”

purchases; and (ii) from the PBMs to the pharmacies for the purchases made by health plans' members. ¶¶ 168-71.

The AMCC alleges that Defendants inflate AWP's so that medical providers who purchase the drugs at a low cost can bill Medicare at the inflated AWP's and earn a substantial profit or "spread" between the real cost and the AWP reimbursement. ¶ 161. Defendants also inflate AWP's in order to influence the drug formulary decisions of the PBMs, which frequently pocket the "spread" between a discounted AWP that the PBM agrees to pay retail pharmacies, and the AWP at which the health plans reimburse the PBM. ¶ 171. The AMCC alleges that "[t]he purpose of artificially inflating the PBMs' profits was to create an illegal kickback to the PBMs, funded by health plan and subscriber overpayments," the latter in the form of inflated co-payments.⁵ ¶ 172. Thus,

in a perversion of the type of competitive behavior expected in a market not subject to illegal manipulation, the Defendant[s] often promote their drugs not based on lower prices, but by the use of reimbursement rates based on a fictitious and inflated AWP that allows purchasers and intermediaries (including providers and PBMs) to make inflated profits – and the Defendant[s] to increase their market share – at the expense of Plaintiffs and the Class. [¶ 6.]

Defendants also employ other devices to create artificial "spreads" and incentives to push their drugs. These include free goods marketed as a way to lower the providers' actual cost of Covered Drugs, volume discounts, rebates, off-invoice pricing, credit memos, consulting fees, debt forgiveness and educational and promotional grants designed to lower the provider's net cost of purchasing the drugs. The AMCC further explains that Defendants kept the value of these incentives "off the book" so that they would not be reflected in the AWP thereby, again, effectuating over-reimbursement for the applicable drugs. ¶¶ 166-67.

⁵ The PBMs also negotiate rebates with Defendants at a percentage of the drug's list price or AWP, and these rebates are not disclosed to the PBM's plan sponsor. Thus, Defendants further inflate AWP's in order to create additional proceeds that are then passed back to the PBMs as "rebates," rather than to the PBM's plan sponsor. ¶¶ 654-57.

In sum, the AMCC alleges that Defendants have manipulated the AWP systems in an unlawful manner by fraudulently and deceptively reporting inflated average wholesale prices. The AWPs for the drugs at issue were simply fabricated in furtherance of Defendants' scheme to generate profit spreads to providers, PBMs and others and to increase Defendants' profits at the expense of Plaintiffs and the Class members. (This conduct is sometimes called Defendants' "AWP Scheme".)

B. The Government Investigations Into Defendants' AWP Scheme

The AMCC alleges that the fraudulent reimbursement scheme engaged in by Defendants is prohibited under federal and state law and is the subject of aggressive federal and state investigations and prosecutions. Congress and regulators of federally-funded health care programs have expressed shock at the recent revelations resulting from investigations into drug manufacturer manipulation of stated average wholesale prices, as well as outrage at the vast degree of the inflation, its purposeful use to market spreads in order to change prescription behavior and usage, and its use to disguise unlawful kickbacks and hidden payments. *E.g.*, ¶¶ 156-57.

Furthermore, in April of this year, the Office of the Inspector General at the United States Department of HHS ("OIG") issued a report explaining that the AWP must be a meaningful figure that is not artificially inflated:

Where appropriate, manufacturers' reported prices should accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers. Any discount, price concession, or similar benefit offered on purchases of multiple products should be fairly apportioned among the products (and could potentially raise anti-kickback issues). Underlying assumptions used in connection with reported prices should be reasoned, consistent, and appropriately documented, and pharmaceutical manufacturers should retain all relevant records reflecting reported prices and efforts to comply with federal health care program requirements. [¶ 153.]

The OIG also rejected the notion – advanced by Defendants here – that purposeful AWP manipulation was a lawful practice:

If a pharmaceutical manufacturer purposefully manipulates the AWP to increase its customers' profits by increasing the amount the federal health care programs reimburse its customers, the anti-kickback statute is implicated Under the anti-kickback statute, offering remuneration to a purchaser or referral source is improper if one purpose is to induce the purchase or referral of program business. ***In other words, it is illegal for a manufacturer knowingly to establish or inappropriately maintain a particular AWP if one purpose is to manipulate the "spread" to induce customers to purchase its product.***

In the light of this risk, we recommend that manufacturers review their AWP reporting practices and methodology to confirm that marketing considerations do not influence the process. Furthermore, manufacturers should review their marketing practices. ***The conjunction of manipulation of the AWP to induce customers to purchase a product with active marketing of the spread is strong evidence of the unlawful intent necessary to trigger the anti-kickback statute.*** Active marketing of the spread includes, for example, sales representatives promoting the spread as a reason to purchase the product or guaranteeing a certain profit or spread in exchange for the purchase of a product. [¶ 154 (emphasis added).]

That Congress has not sanctioned this practice is also revealed by the actions of Abbott Laboratories, a Defendant here, when its related entity TAP Pharmaceuticals agreed to pay \$875 million to resolve criminal charges and civil liabilities in connection with its fraudulent pricing and marketing practices for the drug named Lupron®, which included AWP inflation. At a hearing in the criminal matter, United States District Court Judge William G. Young found:

This has been a gross abuse of the Medicare/Medicaid repayment system, knowing, intelligent. You have demonstrated, and it's all been confirmed in open court, and I don't want anyone forgetting about the fact that this company, not under its present management, knowingly abused the public trust in a most, and I use my words carefully, despicable way.

United States v. TAP Pharm. Prods., Inc., No. CR-01-10354-WGY (D. Mass., Dec. 6, 2001).⁶

¶ 509.

⁶ The TAP Defendants have been sued in a separate class action in connection with their fraudulent pricing and marketing practices for Lupron®. ¶ 508.

C. Defendant-Specific Unlawful Conduct

The AMCC sets forth many examples of AWP inflation engaged in by specific Defendants for particular drugs. These allegations, which span 133 pages, are not repeated here. See AMCC at pp. 200-383. However, the following examples again show Defendants' specific participation in the AWP scheme:

-- *Regarding Abbott*: "The evidence . . . clearly shows that Abbott has intentionally reported inflated prices and has engaged in other improper business practices in order to cause its customers to receive windfall profits from Medicare and Medicaid when submitting claims for certain drugs. The evidence further reveals that Abbott manipulated prices for the express purpose of expanding sales and increasing market share for certain drugs." (10/31/00 Letter, Stark to White), ¶ 203.

-- *Regarding Aventis Group*: "The following chart represents a comparison of Hoechst's fraudulent price representations for its injectable form of the drug versus the truthful prices paid by the industry insider And this underscores the frustration that federal and state regulators have experienced in their attempts to estimate the truthful prices being paid by providers in the marketplace for prescription drugs" (9/28/00 Letter, Stark to Holmer), ¶ 264.

-- *Regarding Baxter*:

[REDACTED]

-- *Regarding Bayer*: "The government's investigation of the allegations . . . revealed that [Bayer] beginning in the early 1990s falsely inflated the reported drug prices – referred to by the industry as the Average Wholesale Price (AWP)" (1/23/01 Press Release, DOJ), ¶ 287.

-- *Regarding Dey*: "Medicare's reimbursement amount for albuterol was nearly six times higher than the median catalog price" and that "Medicare and its beneficiaries would save between \$226 million and \$245 million a year if albuterol were reimbursed at prices available to suppliers." (OEI-03-01-00410, March 2002), ¶ 356.

-- *Regarding GlaxoSmithKline*:

[REDACTED]

D. The Pervasive Damage Caused by Defendants' AWP Scheme

Government payors have not been the only targets of Defendants' AWP Scheme. Private individuals and businesses have also suffered damage as a direct result of Defendants' AWP Scheme. Damage has been directly inflicted on, among others: (i) Plaintiffs and other third-party payor Class members who reimburse health care providers or make payments to PBMs for prescription drugs based upon the AWP; (ii) Plaintiffs and Class members who make prescription drug co-payments under their health insurance plans; (iii) Plaintiffs and Class members who make Medicare Part-B prescription drug co-payments; and (iv) Plaintiffs and Class members who pay in full for prescription drugs. ¶¶ 139-40, 541.

E. Plaintiffs' Causes of Action

Plaintiffs bring claims on behalf of two Classes as follows:

AWP Payor Class:

All persons or entities who, for purposes other than resale and during the Class Period, paid any portion of the purchase for a prescription drug manufactured by a Defendant Drug Manufacturer (as identified in Appendix A) at a price calculated by reference to the published AWP during the Class Period.

Sub-Class: The PBM Third-Party Payor Class:

All Third-Party Payors that, during the Class Period, contracted with a PBM to provide to its participants a prescription drug manufactured by a Defendant Drug Manufacturer and identified in Appendix A.

⁷ Plaintiffs reserve the right to modify the Class Definition based on class related discovery and/or merits discovery.

⁸ Plaintiffs also bring claims related to the Together Rx Card Scheme on behalf of two additional classes, which is discussed in a companion opposition memorandum.

The AMCC contains ten Counts that are succinctly summarized as follows:

Count	Summary of Count
I	Asserts claims under 18 U.S.C. § 1962(c) for violating RICO. In this Count, Plaintiffs claim that Defendants engaged in an illegal pattern of racketeering wherein each manufacturer formed a separate association-in-fact enterprise with each of the companies that published their inflated AWP, and that each manufacturer conducted the affairs of each such enterprise. ¶¶ 619-46.
II	Plaintiffs assert claims under 18 U.S.C. § 1962(c) alleging that Defendants engaged in a pattern of racketeering via each manufacturer's separate association-in-fact enterprise with each of the four major PBMs, and that each manufacturer conducted the affairs of its PBM enterprises. ¶¶ 647-79.
III	Seeks declaratory relief declaring the AWP practices described herein to be illegal. ¶¶ 680-83.
IV	Alleging that the AWP inflation scheme violates the consumer protection laws of various states. ¶¶ 684-91.
V-VIII, X	Brought on behalf of a Nationwide End Payor Together Card Class relating to Defendants' Together Rx Card scheme. ¶¶ 699-725, 734-41.
IX	Brought against various Defendants for engaging in a series of separate civil conspiracies with each of the PBMs to artificially inflate AWP. ¶¶ 726-33.

III. THE APPLICABLE STANDARD FOR DISMISSAL

This Court set forth the applicable legal standards on a 12(b)(6) motion in its Order. *AWP*, 263 F. Supp. 2d at 177-78. Of particular importance on this motion is the rule of law that “where the proof is largely in the hands of the [defendant], dismissals prior to giving the plaintiff ample opportunity for discovery should be granted sparingly.” *Hewlett-Packard Co. v. Boston Sci. Corp.*, 77 F. Supp. 2d 189, 195 (D. Mass. 1999). *See also United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp. 2d 39, 47 (D. Mass. 2001) (strict pleading requirements are relaxed where facts underlying the fraud are particularly within the defendant’s control) (Saris, J.).⁹

⁹ As set forth in Plaintiffs’ Memorandum in Support of Motion to Take Limited Additional Discovery, some Defendants have been subject to no discovery and others have produced limited discovery.

Under these standards and for the reasons detailed below, the Court should deny Defendants' motions to dismiss.

IV. THE AMCC SATISFIES AND EXCEEDS THE REQUIREMENTS OF RULE 9(b)

Defendants challenge, for a second time, certain allegations for ostensibly failing to comply with Rule 9(b). In doing so, Defendants misapply applicable Rule 9(b) standards and outright misread the Court's Order.

A. The Requirements of Rule 9(b)

Rule 9(b) requires that "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity." Fed. R. Civ. P. 9(b). An exception to the particularity requirements of Rule 9(b) exists where plaintiffs are not directly involved in the alleged fraudulent scheme and, thus, cannot be expected to have personal knowledge of the facts constituting the fraud. *See Kuney Int'l, S.A. v. Dilanni*, 746 F. Supp. 234, 237 (D. Mass. 1990) (civil RICO claim was pled with sufficient particularity). In such cases, plaintiffs may satisfy Rule 9(b) by including those facts upon which their beliefs are found. *Id.* Indeed, this Court has recognized that "the requirements of 9(b) must be read in conjunction with Rule 8(a)," which requires only a "short and plain statement of the claim." *Parke-Davis*, 147 F. Supp. 2d at 46. The Court has also acknowledged that "where facts underlying the fraud are 'peculiarly within the defendants' control,' a plaintiff may be excused from pleading the circumstances of the fraud with a high degree of precision." *Id.* at 47 (quoting *Boston & Me. Corp. v. Hampton*, 987 F.2d 855, 866 (1st Cir. 1993)). The complaint satisfies Rule 9(b) where "[t]he general outline of the general scheme to defraud . . . provides the defendant with notice of the grounds on which the plaintiff's claim is based." *Kuney*, 746 F. Supp. at 237; *see also Hastings v. Fidelity Mortg. Decisions Corp.*, 984 F. Supp. 600, 607 (N.D. Ill. 1997) ("The [RICO] allegations must be specific enough to provide the defendants with a general outline of how the alleged fraud scheme operated and of their purported role in the scheme."). This is

precisely what the AMCC does here, particularly with respect to the issues invoked by Defendants.

B. The Court Specified How Plaintiffs Should Comply With Rule 9(b)

Recognizing that Plaintiffs had complied with Rule 9(b) as to the general AWP Scheme, the Court directed Plaintiffs to add specificity as follows:

The Court *DENIES* defendants' motion to dismiss with respect to any drug identified in the complaint together with the allegedly fraudulent AWP published by a named defendant for that drug. However, to the extent the complaint seeks to encompass all "brand name drugs" (¶¶ 166, 333), named drugs¹⁰ without a specific fraudulent AWP, or generic multi-source drugs¹⁰ the motion to dismiss is *ALLOWED*. In the event any such amendment is filed, plaintiffs shall clearly and concisely allege with respect to each defendant: (1) the specific drug or drugs that were purchased from defendant, (2) the allegedly fraudulent AWP for each drug, and (3) the name of the specific plaintiff(s) that purchased the drug. [AWP, 263 F. Supp. 2d at 194.]

The AMCC complies with each element of this Order.

C. The AMCC Identifies Each Drug Targeted by Plaintiffs' Claims and Sufficiently Outlines the General Scheme to Defraud

In an Orwellian refrain, Defendants chastise Plaintiffs for seeking to substantially "expand" the case by actually identifying all of the specific drugs at issue. Defs. Mem. at 7. As the Court noted in its Order, the MCC targeted "some Medicare covered drugs; brand name drugs and generic multi-source drugs without identifying the drug." AWP, 263 F. Supp. 2d at 194. The MCC's universe was potentially thousands of drugs. However, the AMCC does not expand the drugs at issue, it *narrows and focuses the case on a finite list of approximately 321 drugs*. For each such drug, it identifies the brand name, generic name (if applicable), National Drug Code ("NDC") number for each dosage and formulation, and the fraudulent AWPs for each drug, usually over multiple years. See ¶ 11 and Appendix A. In addition, the AMCC identifies, in Appendix B thereto, each drug purchased by each Plaintiff to ensure that at least one Plaintiff

¹⁰ AWP, 263 F. Supp. 2d at 194.

has purchased a drug marketed by each Defendant. *See* Order at 43 and Section IX *infra*. And this is *exactly* what the Court ordered Plaintiffs to do when it stated that Plaintiffs must “clearly and concisely allege with respect to each Defendant.” Thus, Defendants’ objection to Plaintiffs’ studied compliance with the letter of this Court’s Order should be quickly rejected.

Nonetheless, Defendants insist that the AMCC lacks the requisite particularity because Plaintiffs: (i) do not identify *every* purchase made by each Plaintiff throughout the Class Period, including the *amount* each Plaintiff actually paid for each drug; (ii) do not identify every single instance in which a Defendant stated a false AWP for each of the Identified Drugs; and (iii) have not stated an AWP for each Identified Drug prior to 1997. Defs. Mem. at 8-9. Importantly, *the Court did not require Plaintiffs to plead these excruciating details*; nor would it. A detailed explanation of the scheme, without pleading every fraudulent act, is acceptable where, as is the case here, the fraudulent scheme involves thousands of fraudulent statements that occurred over a long period of time. And there is no question that Plaintiffs have provided a general explanation of the scheme. *See AWP*, 263 F. Supp. 2d at 178-80. Indeed, this Court has previously rejected defense pleas that a Plaintiff must allege every facet of a complex fraud:

Defendant contends that the pleading of the basic scheme of fraud or the identification of certain instances of fraudulent conduct does not satisfy Rule 9(b). Indeed, Defendant goes so far as to argue that Rule 9(b) requires no less than the identification of every ineligible prescription submitted to the government for payment. This view of Relator’s pleading obligation may fit a scenario where the alleged fraud is confined to a small number of transactions about which Relator had knowledge. However, where the alleged scheme of fraud is complex and far-reaching, pleading every instance of fraud would be extremely ungainly, if not impossible.

Parke-Davis, 147 F. Supp. 2d at 49.

Plaintiffs allege that the AWP’s for each drug are fraudulent for the same reason: they did not reflect any real averages of prices charged for the drug and were designed solely to cause Plaintiffs, the Class members and others to overpay for the drugs. *E.g.*, ¶ 3. As the court stated in *Kuney*, “[t]he additional particularity desired by the defendant, regarding the exact role [he]

played in the scheme to defraud . . . should be left for discovery and is not required to be alleged in the complaint under Rules 8 and 9(b).” 746 F. Supp. at 238.

D. The AMCC Sufficiently Outlines How the Fraud Is Carried Out in the PBM Context

In an argument implicitly rejected by the Court in its Order (*AWP*, 263 F. Supp. 2d at 179-80), Defendants protest that the AMCC does not adequately specify how Defendants perpetrate fraud where PBMs are involved in the delivery of prescription drug benefits. Yet the AMCC precisely identifies the operation of the fraud in the PBM context. As the AMCC explains, PBMs, like Medicare, use the published AWP as pricing benchmarks in their reimbursement systems. ¶ 172. And much like medical providers in the Medicare Part B context, the PBMs retain the spread between the AWP-based price they charge their clients, and the lower price they pay for the drugs. *See AWP*, 263 F. Supp. 2d at 179-80. Thus, Defendants’ AWP Inflation Scheme provides the PBMs with incentives to favor one Defendant’s drug over another; the greater the AWP inflation, the greater the profit to the PBM. ¶¶ 168-78.

A specific example of Defendants’ conspiratorial conduct with PBMs is shown by an agreement between AstraZeneca and PBM Caremark in which AstraZeneca guaranteed that it would maintain a spread between AWP and the average wholesale cost in order to ensure a profit to Caremark at the expense of the Class members. ¶ 236(b).

Defendants need no further details to put them on notice of the “[t]he general outline of the general scheme to defraud” in the PBM context. *Kuney*, 746 F. Supp. at 237. If more details were needed, surely the Court would have required them in the Order. But the Court did not do so and instead was able to fairly and succinctly summarize the nature of the PBM fraud allegations when it wrote:

Plaintiff union and employee health benefit plans contract with drug plan managers, known as Pharmacy Benefit Managers (“PBMs”), which operate as intermediaries between the pharmaceutical companies and the private health plans. These PBMs set prices on their formularies – their drug fee lists – based on the AWP figures reported in the same trade publications used

by the Medicare program, less a certain percentage discount. Again, defendants market the same pricing and reporting “spread” to PBMs that they do to individual health care providers serving Medicare patients. The PBMs are offered drugs at highly “discounted” actual prices while charging the private health plans fees based on the inflated AWP. The PBMs benefit by keeping the “spread” for themselves and the pharmaceutical companies benefit because PBMs are drawn to keeping on their formularies drugs from those companies offering the most lucrative “spreads.”

AWP, 263 F. Supp. 2d at 179-80. No further details are needed but more detail concerning the PBMs’ role is set forth in the AMCC. ¶¶ 168-78.

E. The AMCC’s Allegations of Additional Improper Inducements Are Specific and Sufficient

Defendants’ final challenge based on Rule 9(b) is to recycle yet another failed argument (*see* Defs. Mem. at 10) by objecting to Plaintiffs’ allegations that Defendants used various hidden inducements, such as rebates or gratuities, to effectively lower the price of their drugs and further widen the “spread.” ¶¶ 164-67. The AMCC alleges that most of these inducements were hidden and not revealed to Plaintiffs and Class members, thus making it impossible for Plaintiffs to, absent discovery, plead each and every instance that Defendants used them.¹¹ ¶ 191. Again, Plaintiffs are not required to plead each specific fact in support of their allegations at this stage but rather the general outline of the scheme to put Defendants on notice of their claims. *See Parke-Davis, supra*, 147 F. Supp. 2d at 46-47 (general outline of scheme is sufficient). These are just the type of details that courts recognized “should be left for discovery and [are] not required to be alleged in the complaint under Rules 8 and 9(b).” *Kuney*, 746 F. Supp. at 238; *see also Parke-Davis*, 147 F. Supp. 2d at 47 (discussing relaxation of Rule 9(b) requirements where the information is “peculiarly within the defendants’ control”) (quoting *Boston & Me. Corp. v. Hampton*, 987 F.2d 855, 866 (1st Cir. 1993)).

¹¹ The AMCC also provides specific examples of how certain Defendants attempted to conceal the true prices of their drugs. *See, e.g.*, ¶¶ 228 (Amgen); 271 (Aventis); 301 (Bayer); 362a (misnumbered as 15) (Dey); 435 (Immunex); 445 (J&J); 522-24 (TAP); 540 (Watson).

And in ruling on the MCC, the Court discussed the inducement allegations and did not find them lacking:

For some defendants, the AWP scheme is not the only mechanism used to create the artificial “spreads.” Another method involves the provision of “free samples” to health providers who are sometimes encouraged to bill their customers for the samples as they would any other drug. This “free sample” scheme lowers the providers’ overall costs while not reducing the amount they receive in reimbursements from the federal government, or co-payments from consumers, which remain tied to the reported AWP. Other fraudulent pricing practices include off-invoice pricing, phony consulting fees, as well as debt forgiveness, rebates, and grants. All of these incentives were designed to lower the providers’ net cost of purchasing the drugs. [*AWP*, 263 F. Supp. 2d at 179.]

Furthermore, the AMCC identifies specific improper inducements made by many Defendants.

For example, the AMCC specifically alleges that:

- Amgen provided hidden rebates on its Epogen (§ 225);
- Astrazeneca provided free goods for purchases of Zoladex (§ 247);
- Baxter provided free goods as a means to effectively reduce the price of its recombinant products (§ 284);
- Bayer discounted the price of its Kogenate product through a form of bogus marketing or educational grants (§ 298);
- BMS provided free Etopophos to certain doctors as an incentive and provided free medical equipment as an additional way to effectively lower the price of other cancer drugs (§ 340);
- Dey offered its customers free goods of its coromolyn sodium products based on their purchase amounts (§ 362);
- SmithKline offered to contribute to research and education programs if certain customers purchased its Kytril instead of a competing drug (§ 414);
- Pharmacia specifically directed its oncology sales representatives to offer free product to customers to obtain sales of its Adriamycin products (§ 474);
- TAP provided free goods and various other incentives, including all expenses paid, weekend trips to luxury resorts, to physicians to induce them to use TAP products (§§ 515-19); and
- Watson specifically offered “off invoice” discounts for certain purchases of its Ferrlecit product (§ 538).

Thus, while Plaintiffs have not yet uncovered or set forth in the AMCC every evidentiary item showing every improper inducement offered by Defendants to increase spreads over the past several years, Plaintiffs have detailed the types of inducements being offered, and the broad role such inducements play in the AWP fraud. This is more than adequate to put all of the Defendants on notice of Plaintiffs' claims and complies with Rule 9(b). As before, the Court should reject Defendants' challenge to the specificity of these allegations.

V. COUNTS I AND II PROPERLY PLEAD RICO VIOLATIONS

A. An Overview of Plaintiffs' Civil RICO Claims and Their Necessary Elements

Counts I and II assert two separate substantive claims against Defendants for violations of Section 1962(c) of RICO.¹² Count I (§§ 619-46) asserts claims on behalf of the AWP Payor Class, while Count II (§§ 647-79) asserts claims on behalf of the PBM Third-Party Payor Sub-Class. Each count properly alleges all elements required by the statute, First Circuit precedent, the Court's Order, Rule 8(a) and, where applicable, Rule 9(b).

Section 1962(c) of RICO makes it "unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity. . . ." 18 U.S.C. § 1962(c). Thus, Plaintiffs must prove these elements: (i) an enterprise existed; (ii) the enterprise participated in, or its activities affected, interstate commerce; (iii) the defendant was employed by or was associated with the enterprise; (iv) the defendant conducted or participated in the conduct of the enterprise; (v) through a pattern of racketeering activity. *United States v. Marino*, 277 F.3d 11, 33 (1st Cir. 2002) (citing *United States v. Shifman*, 124 F.3d 31, 35 (1st Cir. 1997)); see also *N. Bridge Assocs., Inc. v. Boldt*, 274 F.3d 38, 42 (1st Cir. 2001).

¹² Plaintiffs also bring a third civil RICO claim in Count VIII (related to the Together Rx Card fraud), but Defendants chose to challenge Count VIII in a separate memorandum related solely to Plaintiffs' Together Rx fraud allegations. Consequently, Plaintiffs separately address Defendants arguments against Count VIII in another brief and will not repeat those arguments here. The argument that follows is confined to Counts I and II.

The following chart summarizes the requisite elements of Plaintiffs' civil RICO claims and where each element is alleged:

Elements of Civil RICO Claims:	<u>Count I</u> ¶¶ 619-46	<u>Count II</u> ¶¶ 647-79
"Persons"	¶¶ 621-22	¶¶ 649-50
"Enterprise(s)"	¶¶ 624-28 (Manufacturer-Publisher Enterprises)	¶¶ 651-61 (Manufacturer-PBM Enterprises)
"Racketeering Activity"	¶¶ 637, 629-33 (Mail/Wire Fraud)	¶¶ 670, 662-66 (Mail/Wire Fraud)
"Pattern of Racketeering Activity"	¶¶ 637-41	¶¶ 670-74
"Conduct" of Enterprise(s)	¶¶ 624-27, 634-36	¶¶ 651-60, 667-69
"Defendants' Motive"	¶¶ 642-43	¶¶ 675-76
"Plaintiffs' Injury"	¶¶ 644-46	¶¶ 677-79

For Counts I and II, Defendants challenge only the three elements shaded in the above table: (i) definition of the enterprises; (ii) conduct of the enterprises; and (iii) proximate cause. Accordingly, Plaintiffs limit further discussion of Counts I and II to these three elements.

B. The AMCC Properly Identifies the RICO Enterprises

1. The RICO "Enterprise" concept

"Enterprise" is defined broadly to include "any individual partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact though not a legal entity." 18 U.S.C. § 1961(4). Thus, to satisfy the "enterprise" element, Plaintiffs must allege "either the existence of a legal entity, such as a corporation, or that a group of individuals were associated-in-fact." *Aetna Cas. Sur. Co. v. P&B Autobody*, 43 F.3d 1546, 1557 (1st Cir. 1994). An association-in-fact enterprise is an "ongoing organization," whether "formal or informal," with members "function[ing] as a continuing unit," which is "separate and apart from the pattern of activity in which it engages." *United States v. Turkette*, 452 U.S. 576, 583 (1981). An association-in-fact RICO enterprise may consist of "two or more legal entities," or "two legal entities and two individuals." *United States v. London*, 66 F.3d 1227, 1243 (1st Cir. 1995). The First Circuit and this Court have expressly rejected an "ascertainable structure" enterprise requirement. See *United States v. Patrick*, 248 F.3d 11, 18-19 (1st Cir.) ("Since

Congress intended the term ‘enterprise’ to include both legal and criminal enterprises, . . . and because the latter may not observe the niceties of legitimate organizational structures, we refuse to import an ‘ascertainable structure’ requirement into jury instructions.”), *cert. denied*, 534 U.S. 1043 (2001), *cert. denied*, 535 U.S. 910 (2002); *London*, 66 F.3d at 1244 (association-in-fact enterprise consisting of corporation and sole proprietorship engaged in bookmaking and extortion); *AWP*, 263 F. Supp. 2d at 182.

Among the factors cited by the First Circuit in determining whether a RICO association-in-fact enterprise has been properly alleged, the Court noted the following: (i) whether the associates have a common purpose (citing *Libertad v. Welch*, 53 F.3d 428, 442-43 (1st Cir. 1994)); (ii) whether there is “systematic linkage,” such as overlapping leadership, structured or financial ties or continuing coordination (citing *id.* at 443); (iii) whether there is a common communication network for sharing information on a regular basis (citing *id.* at 444); (iv) whether the associates hold meetings and sessions where important discussions take place (citing *Patrick*, 248 F.3d at 19); (v) whether the associates wear common colors, signs or insignia to make the group identifiable (citing *id.*); and (vi) whether the group conducted common training and instruction (citing *id.*). *AWP*, 263 F. Supp. 2d at 183. The Court expressly clarified that no one factor was dispositive. *Id.*

As set forth below, as to each of the association-in-fact enterprises that are alleged in Counts I and II of the AMCC, Plaintiffs have specifically alleged the relevant criteria to demonstrate the existence of the enterprise and identify its associates, as required by this Court and by the First Circuit. *See AWP*, 263 F. Supp. 2d at 183.

2. The Manufacturer-Publisher Enterprises

In the MCC, Plaintiffs previously alleged Publisher Enterprises, which this Court described as “associations-in-fact comprised of each of the [drug manufacturers] and the publishers that reported their AWP.” *Id.* at 184. Under these prior allegations, the Court found that each of these enterprises consisted of one pharmaceutical company as the “hub” and “each

of the [four] major publishers that reported the AWP's provided to them by the [pharmaceutical] company as the spokes." *Id.* The Court found that this definition suffered from a failure of connectedness and common purpose, *id.* at 184-85, the so-called "hub-and-spoke" or "rimless wheel" problem.

In Count I of the AMCC, Plaintiffs have addressed and eliminated the Court's concern. Plaintiffs now allege a separate association-in-fact enterprise consisting of a single pharmaceutical company and a single publisher (a "Manufacturer-Publisher Enterprise"). ¶ 624. For example, in Count I, Abbott is alleged to have been a member of three separate association-in-fact Manufacturer-Publisher Enterprises: the Abbott-Thomson Medical Enterprise; the Abbott-First DataBank Enterprise; and the Abbott-Facts & Comparisons Enterprise. ¶ 628(a).¹³ As a result, Count I of the AMCC now alleges 66 separate Manufacturer-Publisher Enterprises. Thus, the so-called "rimless wheel" has been eliminated.

Unsatisfied, Defendants maintain that Plaintiffs have still failed to allege that the Manufacturer-Publisher Enterprises constitute ongoing organizations whose members function as continuing units and share common purposes. Defs. Mem. at 14-17.¹⁴ Defendants are simply wrong.

a. Plaintiffs allege that each Manufacturer-Publisher Enterprise has an ongoing, continuing structure separate and apart from the racketeering activity

Count I alleges that each of the Manufacturer-Publisher Enterprises "is an *ongoing* and *continuous* business organization consisting of both corporations and individuals," ¶ 624 (emphasis added), where the participants "agree[d] to a structure wherein the manufacturers made decisions as to what AWP's would be reported." ¶ 627. Each of the Manufacturer-Publisher Enterprises has a "systemic linkage" through "contractual relationships, financial ties,

¹³ The respective Manufacturer-Publisher Enterprises for the other Defendants are defined in ¶¶ 628(b)-(v).

¹⁴ Defendants do *not* contend that Plaintiffs have failed to identify liable "persons" that are "distinct" from the RICO "enterprises," a requirement for pleading Section 1962(c) claim. See *Trustees of Boston Univ. v. ASM Comm., Inc.*, 33 F. Supp. 2d 66, 73-74 (D. Mass. 1998) (Saris, J.).

and continuing coordination of activities” including a “common communication network by which the Defendant Drug Manufacturer and the specific Publisher share information on a regular basis” by, typically, “a manufacturer . . . instruct[ing] a publisher to list a certain AWP.” ¶ 625.

Further, the AMCC explains that each Defendant Drug Manufacturer sits at the top of the hierarchical decision-making structure and “made decisions as to what AWP’s would be *reported*,” ¶ 627, and “issued instructions on how its AWP’s were to be *reported* and each publisher accepted those instructions despite knowing of their falsity.” ¶ 635 (emphasis added). Each of the Defendant Drug Manufacturers, from the top of the enterprise, “conducted the affairs of each of the Manufacturer-Publisher Enterprises with which they associated by *reporting* fraudulently inflated AWP’s for AWPIDs that were then published by the Publishers and disseminated nationwide.” ¶ 636 (emphasis added).

Thus, Defendants’ feigned cries that Plaintiffs failed to “plead a single fact” (i) showing an ongoing and continuing business organization and (ii) “describing [the hierarchical decision making] structure,” Defs. Mem. at 15-16, are belied by the AMCC’s repeated reference that each Defendant Drug Manufacturer *reported* fraudulent AWP’s to the Publishers that then published those numbers.¹⁵ Plaintiffs have plainly alleged enterprises that “exhibit structural continuity which exists where there is an organizational pattern or system of authority that provides a mechanism for directing the group’s affairs on a continuing, rather than an ad hoc, basis.” *Manhattan Telecomms. Corp. v. DialAmerica Mktg.*, 156 F. Supp. 2d 376, 381-82 (S.D.N.Y. 2001) (cited by Defendants).

Furthermore, Defendants claim that “[a] RICO enterprise cannot consist of merely two separate entities engaged in a common business venture,” Defs. Mem. at 17, but Defendants are

¹⁵ Even though Plaintiffs alleged the existence of an hierarchical decision-making structure headed by each Defendant Drug Manufacturer, the First Circuit does not even require that such an allegation be made. *See Patrick*, 248 F.3d at 18 (rejecting defendant “street gang” members’ appeal based on district court’s refusal to instruct the jury that “at a minimum, the enterprise must exhibit some sort of structure for the making of decisions, whether it be hierarchical or consensual”). Thus, Plaintiffs have gone well beyond the First Circuit’s enterprise pleading requirements.

squarely wrong. As this Court has already recognized, “*two* or more legal entities *can* form or be part of an association-in-fact RICO enterprise.” *AWP*, 263 F. Supp. 2d 182 (emphasis in original) (citing cases). Indeed, in *United States v. London*, 66 F.3d at 1243 (cited by the Court here), Senior Judge Bownes noted that Defendants’ proffered reading of RICO’s “enterprise” element “would lead to the bizarre result that only criminals who failed to form corporate shells to aid their illicit schemes could be reached by RICO.” *Id.* at 1244. Thus, the association-in-fact in *London* consisting of a bar and a check-cashing business – both legitimate businesses in their own right – sufficed as a RICO enterprise. *Id.*

The same is true here. An individual Defendant Drug Manufacturer and an individual Publisher are separate legal entities, each conducting their own respective businesses of (i) manufacturing and selling drugs and (ii) publishing AWP’s for drugs.¹⁶ The enterprise was formed when – in a concerted break with past practice – the Defendant Drug Manufacturers began reporting fraudulent AWP’s, and the Publishers began publishing them without independent verification. ¶ 626. Plaintiffs have properly alleged that each Manufacturer-Publisher Enterprise had an existence separate and apart from the racketeering activity in question.¹⁷

¹⁶ The businesses conducted by each of the Publishers are considerably broader than just publishing AWP’s. For instance, First DataBank sells a host of “healthcare knowledge” databases, various application development tools and specialty software. See www.firstdatabank.com. Likewise, Facts & Comparisons, Inc. publishes a wide variety of drug reference products in addition to AWP information, including drug interaction facts and formulary monographs. See www.factsandcomparisons.com. Thomson Medical Economics, a third Publisher, “provides nearly 170 high-quality healthcare information products and services, including magazines, directories, references, newsletters, and online services” in addition to publishing AWP’s. See www.medec.com/html/products/index.html.

¹⁷ Defendants rely on a footnote in the First Circuit’s decision in *Feinstein v. Resolution Trust Corp.*, 942 F.2d 34, 42 (1st Cir. 1991), which dismissed a civil RICO claim because plaintiffs’ complaint merely “made a ritualistic averment, in wholly conclusory terms” that defendants formed an association-in-fact enterprise. Defs. Mem. at 14. Such allegations were insufficient because plaintiffs’ complaint “contained no allegations articulating how any of the [defendants] may have comprised part of an ‘ongoing organization’ or ‘functioned as a continuing unit.’” *Id.* (quoting *Turkette*, 452 U.S. at 583). *Feinstein* is readily distinguished from this case by comparing the paltry allegations at issue in that case with the detailed allegations found in ¶¶ 624-28 and 634-36.

b. Plaintiffs allege that each Manufacturer-Publisher Enterprise has a common purpose

The MCC did not state how the manufacturers and publishers shared a common purpose – other than greed. *AWP*, 263 F. Supp. 2d at 183-84. However, in the AMCC, in detailed allegations, Plaintiffs assert that each Manufacturer-Publisher Enterprise has a common purpose of profiting from the publication of false and misleading AWP. ¶ 624. The Defendant Drug Manufacturers “have this as a purpose because without the AWP scheme, they would not be able to push the spread.” *Id.* And the “publishers agree to this scheme, because if they did not, the manufacturers could easily revert to the other methods of publishing prices or the publishers would have to independently investigate the AWP at significant expense.” *Id.* Thus, the AMCC explains that the Publishers

have an economic incentive to merely report the AWP provided to them by the manufacturers, because to do otherwise would require the Publishers to spend money to extensively survey actual sales prices in the market. By simply republishing what is submitted to them by the drug manufacturers, ***the Publishers save on expenses and consequently reap greater profits.***

Id. (emphasis added).

This allegation thus provides the purpose the Court found lacking. *AWP*, 263 F. Supp. 2d at 185. Unlike the MCC, which failed to allege that members of the enterprises associated for a common fraudulent purpose (*see, e.g., id.* at 184), the AMCC identified each Publisher’s joinder in the publication of inflated AWP. ¶ 626. For instance, at some point prior to 1992, the Publishers in many instances obtained AWP themselves by surveys that they conducted. Based on this survey experience, the Publishers know that the AWP now being reported by the manufacturers are not accurate. ¶ 626.

The Publishers’ knowledge of various government agency reports of AWP inflation also highlights their participation in the wrongdoing and the common purpose that the Publishers share with the Defendant Drug Manufacturers. With one exception, the Publishers did not change or challenge the self-reported AWP, but continued blindly accepting the requested

AWPs, notwithstanding their knowledge of the government reports. ¶ 626. The one exception involves the reporting by Dey of inflated AWP. When the State of Texas prosecuted Dey for its AWP practices, and when other states began focusing on Dey, the Publishers very recently stopped accepting Dey's reported AWP and published a different, far lower AWP for certain Dey drugs. They withdrew from the Dey enterprise due to fear that they would be sued if they continued to publish Dey's false AWP. This, in turn, prompted a lawsuit by Dey alleging that the Publishers were treating Dey *differently* than they were treating all other manufacturers. In other words, Dey was complaining of the others being allowed to continue the scheme while it could not. ¶ 626.

Thus, the Publishers are knowing and willing participants in the AWP Inflation Scheme and reap profits from that scheme that they otherwise would not absent the unlawful conduct. The same is true of the Defendant Drug Manufacturers. This is precisely the type of common and shared purpose inherent in the RICO enterprise requirement, and, under the First Circuit's decision in *United States v. London*, these allegations suffice. In *London*, the criminal RICO defendant operated a bar (Heller's) and a check-cashing service (M & L). 66 F.3d at 1230. The alleged RICO enterprise was an association-in-fact between Heller's (a corporation) and M & L (a sole proprietorship). *Id.* at 1243. The government charged that London conducted the affairs of the enterprise through a pattern of racketeering activity that included illegal bookmaking and extortion. *Id.* at 1230. Notwithstanding the seemingly unrelated nature of the bar and check-cashing businesses, in affirming London's RICO conviction the First Circuit stated that "[t]he jury could have found that there was a common or shared purpose animating both the enterprise and London: doing commerce with (and thereby profiting from) bookmakers engaged in illegal gambling." *Id.* at 1244; *see also United States v. Cianci*, 210 F. Supp. 2d 71, 74-75 (D.R.I. 2002) (a legal entity need not share the criminal purposes of the individuals controlling it in

order to be part of an association-in-fact enterprise).¹⁸ Defendants and the Publishers share a similar common purpose here of simultaneously profiting from the scheme.

Defendants' reliance upon *Blue Cross v. SmithKline Beecham Clinical Labs., Inc.*, 62 F. Supp. 2d 544 (D. Conn. 1998), is misplaced. Defs. Mem. at 16. In that case, the plaintiff insurance companies and patients who paid for clinical laboratory tests conducted by SmithKline asserted civil RICO claims, contending that SmithKline had engaged in fraudulent billing practices. 62 F. Supp. 2d at 547, 549. Plaintiffs alleged a nationwide "billing network" RICO enterprise consisting of SmithKline, its personnel and the hospitals, physicians, physician practice groups, and laboratories to which the fraudulent bills had been sent. *Id.* at 550. The district court found that the physicians, hospitals and laboratories that had allegedly been fooled by SmithKline's fraudulent billing scheme did not share a "common purpose" with the defendants. *Id.* at 552. The court wrote that plaintiffs' complaint was "devoid of any specific allegation that any physician, hospital, or laboratory shared [defendants'] alleged common purpose to defraud public and private health care payers." *Id.* at 553. Indeed, the plaintiffs in that case alleged that defendants' "scheme exploited the trust of both patients and payers in the physicians, as well as the trust of the physicians in [defendants]." *Id.* at 552.

In contrast, in this case Plaintiffs specifically allege that the Publishers were knowing and willing participants in the AWP Scheme and profited more from the scheme than they would have but for their knowing participation in the scheme. ¶¶ 624-27. Thus, unlike the association-in-fact enterprise at issue in *SmithKline Beecham*, the members of the Manufacturer-Publisher Enterprises here clearly shared a "common purpose."

¹⁸ *Cianci* arose from the criminal RICO prosecution of the mayor of Providence, Rhode Island, a city official and the operator of a private business. The alleged enterprise was an association-in-fact consisting of the individual defendants, Mayor Cianci's political fundraising organization, and various city departments and agencies that defendants used to award contracts and jobs in exchange for bribes and political contributions. *Id.* at 73. Chief Judge Torres refused to dismiss the RICO indictment, even though defendants argued that the alleged association-in-fact enterprise did not have a "common purpose" because "the City and its departments were legitimate entities that did not subscribe to the defendants' alleged criminal objectives." *Id.*

3. The Manufacturer-PBM Enterprises

Plaintiffs have also cured what this Court saw as deficiencies in the previous PBM Enterprises, which were “comprised of an individual drug company at the hub (i.e. Abbot [sic], Amgen, etc.) and a number of *unnamed* pharmacy benefit managers as spokes.” *AWP*, 263 F. Supp. 2d at 184 (emphasis added). Thus, the Court found the same “hub-and-spoke” problem because the MCC “fail[ed] to allege facts which would support an entity consisting of all the PBMs joined with a drug company in a common purpose.” *Id.*

To address these concerns, Count II of the AMCC identifies the four largest PBMs by name: AdvancePCS; Caremark Rx; Express Scripts; and Medco Health.¹⁹ ¶ 650. To eliminate the “hub-and-spoke” problem, Count II alleges, for each of the 22 Defendant Drug Manufacturers, a separate association-in-fact enterprise consisting of a single pharmaceutical company and a single PBM. For example, in Count II, Abbott is alleged to have been a member of four separate Manufacturer-PBM Enterprises: the Abbott-AdvancePCS Enterprise; the Abbott-Caremark Rx Enterprise; the Abbott-Express Scripts Enterprise; and the Abbott-Medco Health Enterprise. ¶ 661(a).²⁰ Count II now alleges 88 separate Manufacturer-PBM Enterprises.

Although Plaintiffs have addressed the Court’s concerns in re-pleading the Manufacturer-PBM Enterprises, Defendants still maintain that Plaintiffs have failed to allege that the Manufacturer-PBM Enterprises constitute ongoing organizations whose members’ function as continuing units and share common purposes. Defs. Mem. at 14-17. Defendants are again wrong, as even a cursory analysis of the AMCC reveals.

a. **Plaintiffs allege that each Manufacturer-PBM Enterprise has an ongoing, continuing structure separate and apart from the racketeering activity**

Count II alleges that each of the Manufacturer-PBM Enterprises “is an *ongoing* and *continuous* business organization consisting of both corporations and individuals,” ¶ 624

¹⁹ These four PBMs comprise 85% of the market served by PBMs.

²⁰ The respective Manufacturer-PBM Enterprises for the other Defendants are defined in ¶¶ 661(b)-(v).

(emphasis added), where the participants “meet on a frequent basis to discuss drug prices, spreads, marketing opportunities and coordination of all of the above.” ¶ 658. Each of the Manufacturer-PBM Enterprises has a “systemic linkage” through “contractual relationships, financial ties, and continuing coordination of activities” including a “common communication network by which the Defendant and the specific PBM share information on a regular basis.” ¶ 653. This common communication network exists for the purpose of implementing the AWP spread scheme, with the Defendant providing financial rewards for activities undertaken by the PBMs that benefit the manufacturers. ¶ 659. Such incentives include the Defendant’s provision of (i) access rebates for placement of products on the PBMs’ formulary; (ii) market share rebates for garnering higher market share than established targets; (iii) administrative fees for assembling data to verify market share results; and (iv) other fees and grants in an effort to promote products. ¶ 657.

Further, the AMCC alleges that each Defendant sits at the top of the hierarchical decision-making structure and provided these rebates and other inducements to encourage the PBMs to place a certain Defendant’s AWPIDs on a PBM formulary or advocate the use of a certain AWPID. ¶¶ 667-68. Each PBM, wanting to receive as many rebates and other inducements as possible, “took instructions and commands from the manufacturers regarding the use of AWP” ¶ 657. Most importantly, the AMCC explains that Defendants control the pricing benchmark in all PBM contracts, because the AWPs reported by the manufacturers form the basis for reimbursement (i) made by health plans to the PBMs for their members’ drug purchases, and (ii) from the PBMs to the pharmacies for the purchases made by health plan members. ¶ 171.

Defendants’ conclusory and unsupported assertions that Plaintiffs failed to allege the existence of an ongoing organization do not withstand careful scrutiny.

b. Plaintiffs allege that each Manufacturer-PBM Enterprise has a common purpose

In detailed allegations, Plaintiffs assert that each Manufacturer-PBM Enterprise has a common purpose of “selling, purchasing, and administering AWPIDs to individual Plaintiffs and Class members and to [class members]” and “perpetuating the use of AWP as a benchmark for reimbursement in the pharmaceutical industry.” ¶¶ 652, 654. Defendants “ha[ve] this as a purpose, because without the use of inflated AWP as an industry price setting benchmark, they would not be able to push the spread to those in the distribution chain.” ¶ 654. “The PBMs share this common purpose, because they are subject to a great deal of control from the manufacturers.” ¶ 654. The PBMs’ traditional source of revenue – charging clients for claims administration – is shrinking, as clients are no longer willing to pay as much for these services. Consequently, the AMCC alleges that PBMs are beholden to drug manufacturers for hidden profit-making schemes falling into three broad categories:

- (i) garnering rebates and other “soft dollars” from drug manufacturers that the PBM[s], to a large extent, keep without disclosing to their health plans the true amounts of the rebates;
- (ii) pocketing secret spreads between actual drug costs and the prices charged to health plans and their members; and (iii) keeping secret discounts provided by the drug manufacturers in association with the PBMs’ mail order operations. [¶ 654.]

As a result of their reliance on the manufacturers for the bulk of their revenue streams, PBMs took instructions and commands from the manufacturers regarding the use of AWP, not only so that they could keep part of the spread, but also so as to continue to earn rebates and other soft dollars from the manufacturers. ¶ 657. And the PBMs did not disclose to their clients the full extent of rebates earned. Although PBMs typically agree to share rebates in some form with clients, they link the rebates to formulary savings in such a manner that the PBM often is able to secretly retain all of the rebates. PBMs refuse to disclose specific rebate amounts to clients in any fashion other than in the aggregate compared to performance standards, thereby preventing the client from learning the true amount of rebates that the PBM has received in

connection with the health plan client. ¶ 657. Simply put, the PBMs are willing participants in the enterprise, sharing common purposes with the Defendant Drug Manufacturers. ¶ 656.

Defendants assert that Plaintiffs failed to “provide not a single fact to support the conclusion that PBMs share this purpose [of perpetuating use of AWP as a benchmark for reimbursement in the pharmaceutical industry],” Defs. Mem. at 19, yet the above allegations do exactly that. Of course, PBMs share this purpose when “pocketing secret spreads between actual drug costs and the prices charged to health plans and their members.” ¶ 654. *See also* ¶ 175 (“[T]he PBM frequently pockets a “spread” or differential between charges paid to pharmacies and collected from clients. So, for example, clients may be charged the AWP minus 13 percent, but the retail pharmacy may only receive the AWP minus 15 percent, generating an undisclosed 2 percent spread for the PBM.”). Defendants’ argument that they do not share a common purpose with the PBMs based on the allegations of the AMCC is simply wrong.

C. The AMCC Properly Alleges That Defendants Conducted the Affairs of the Manufacturer-Publisher and Manufacturer-PBM Enterprises

Section 1962(c) requires the defendant “to conduct or participate, directly or indirectly, in the conduct of [the] enterprise’s affairs” The Supreme Court has interpreted this to mean that the defendant play “*some* part in directing the enterprise’s affairs.” *Reves v. Ernst & Young*, 507 U.S. 170, 179 (1993) (emphasis in original). Known as the “operation or management test,” this requires “a degree of direction,” which can be direct or indirect. *Aetna Cas. Sur. Co. v. P&B Autobody*, 43 F.3d at 1559. Thus, the First Circuit held that the “operation or management test” was satisfied where defendants caused Aetna appraisers to approve false claims: “[s]ince a reasonable jury could find that the [defendants] exerted *some* control over Aetna and took part in directing *some* aspect of the enterprise’s affairs, the [defendants’] actions could be found to have satisfied the ‘operation or management’ test.” *Id.* at 1560 (emphasis added).²¹

²¹ In *Aetna*, the plaintiff insurance company brought a civil RICO action alleging that defendants had participated in the affairs of Aetna (the enterprise) through a pattern of racketeering activity. 43 F.3d at 1558. The defendants were an automobile body shop, the owner and employees of the body shop, and relatives and friends of the owners and employees of the body shop who submitted false claims to Aetna for supposed repairs done by the

With respect to the Manufacturer-Publisher Enterprises, and as noted above, the AMCC alleges that Defendants controlled and participated in the enterprises through “contractual relationships, financial ties, and continuing coordination of activities” including a “common communication network by which the Defendant Drug Manufacturer and the specific Publisher share information on a regular basis” by, typically, “a manufacturer . . . instruct[ing] a publisher to list a certain AWP.” ¶ 625. As detailed above, the AMCC reiterates many times that each Defendant controlled the Manufacturer-Publisher Enterprises by making decisions as to what AWP’s would be reported and issuing instructions on how its AWP’s were to be reported. *See* ¶¶ 627, 635-36. Other allegations leave no doubt that each Defendant controls each of its respective Manufacturer-Publisher Enterprises by reporting to the Publisher the AWP:

In periodically announcing the AWP for each drug, during the time period relevant to this Complaint the Publishers publish the prices that are supplied to them by the Defendant Drug Manufacturers for their respective drugs. For instance, the forward to the 1999 edition of the *Red Book* states that “all pricing information is supplied and verified by the products’ manufacturers, and it should be noted that no independent review of those prices for accuracy is conducted.” In addition, a June 1996 Dow Jones news article reported that Phil Southerd, an associate product manager of the *Red Book*, stated that it only publishes prices that are faxed directly from the manufacturer. Thus, the Defendant Drug Manufacturers control the prices listed as the AWP’s for each drug listed by the Publisher.

¶ 136.²²

Turning to the Manufacturer-PBM Enterprises, the AMCC’s allegations of control and participation are equally manifest. As noted above, Defendants controlled and participated in the enterprises through “contractual relationships, financial ties, and continuing coordination of

body shop on certain vehicles. Also named as defendants were two Aetna appraisers who, *inter alia*, “submitted false claims to help [the other defendants] defraud Aetna.” *Id.* at 1552.

²² *See also* ¶ 137 (“The Defendant Drug Manufacturers knew that they could directly control and fabricate the AWP for their drugs at any time by forwarding to the Publishers a phony AWP.”); ¶ 634(b) (“Each of the Defendant Drug Manufacturers has directly controlled the AWP’s that are reported by the Publishers[.]”); ¶ 634(e) (“Each of the Defendant Drug Manufacturers intended that each of the Publishers would (and did) distribute their publications containing false AWP’s through the U.S. mails and by interstate wire facilities[.]”); ¶ 634(f) (“Each of the publishers has allowed these Defendants to exert control over their organizations knowing that the AWP’s were inflated and were not real numbers. Each publisher did so because the reporting of AWP’s was, and is, a major part of its business [.]”).